

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-1971V

UNPUBLISHED

EILEEN SMESTAD,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: March 14, 2023

Special Processing Unit (SPU);
Findings of Fact; Site of Vaccination;
Onset; Influenza (Flu) Vaccine;
Shoulder Injury Related to Vaccine
Administration (SIRVA)

Jessica Olins, Maglio Christopher & Toale, PA, Washington, DC, for Petitioner.

Matthew Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On December 23, 2020, Eileen Smestad filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration (“SIRVA”), a defined Table injury, which was causally related to an adverse reaction to the influenza (“flu”) vaccine she received on October 25, 2019. Petition at 1, ¶¶ 6, 16, 19.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the flu vaccine was most likely administered in Petitioner's right shoulder, as alleged, and that onset of Petitioner's pain occurred within 48 hours of vaccination.

I. Relevant Procedural History

During the three months following the filing of her petition, Ms. Smestad filed a signed declaration³ and the medical records required under the Vaccine Act. Exhibits 1-12, ECF Nos. 5-6, 9; see Section 11(c). In her signed declaration, Petitioner addressed the vaccine record initially provided, which listed the site of vaccination as her *left* rather than *right* arm. Exhibit 9. Claiming this designation was incorrect, she stated that since the removal of lymph nodes under her left arm during a bi-lateral mastectomy, she has consistently requested a right arm administration for any vaccine. *Id.* On March 15, 2021, the case was activated and assigned to the Special Processing Unit (OSM's process for attempting to resolve certain, likely-to-settle claims (the "SPU")). ECF No. 10.

Thereafter, Petitioner filed updated medical records and worked to finalize her demand. Exhibits 13-16, ECF Nos. 13-15, 22; Status Report, filed Mar. 21, 2022, ECF No. 23. In April 2022, she provided a second signed declaration, as well as a signed declaration from her husband who was present – receiving his own flu vaccine, when the vaccine alleged as causal was administered.⁴ Exhibits 17-18, ECF No. 24.

On May 2, 2022, Respondent filed a Rule 4(c) Report, opposing compensation in this case. ECF No. 25. Among other things, Respondent argues that Petitioner has not demonstrated that she received the vaccine alleged as causal in her injured, right arm or shown a pain onset within 48 hours as required for a Table SIRVA injury. *Id.* at 8-12; see 42 C.F.R. § 100.3(a) XIV.B. & (c)(10)(ii) (pain onset requirement). Regarding situs, he emphasizes evidence which undercuts Petitioner's claim that she always requests a right arm situs - entries in the medical records indicating prior vaccines were administered in Petitioner's left deltoid. *Id.* at 8-9.

Thereafter, Petitioner filed additional evidence related to the site of vaccination, including medical records regarding her prior breast cancer surgery, a signed declaration from a friend⁵ who usually accompanies Petitioner when obtaining vaccinations and recalled the circumstances surrounding an earlier vaccination on October 21, 2016, and

³ Petitioner's statement comports with the requirements of 28 U.S.C.A. § 1746.

⁴ Both declarations are signed under penalty of perjury as required by 28 U.S.C.A. § 1746.3

⁵ This declaration also is signed under penalty of perjury as required by 28 U.S.C.A. § 1746.

additional vaccine documentation related to multiple vaccinations - including the one alleged as causal in this case, which was obtained in response to granted subpoena authority. Exhibits 19-25. ECF Nos. 28, 30-31.

II. Issue

At issue is whether (a) Petitioner received the vaccination alleged as causal in her injured right arm, and (b) Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as required in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (2017) (Table entry for SIRVA following the influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Findings of Fact

I make the following findings regarding site of vaccination and onset after a complete review of the record, including medical records, signed declarations, and other additional evidence filed showing:

- In 2016, Petitioner experienced right shoulder, neck, and arm pain thought to be due to conditions such as cervical radiculopathy, degenerative disc disease, right shoulder osteophytes,⁶ a lesion of the upper ulnar nerve, tendinitis, and a possible elbow injury. Exhibit 3. Petitioner also believed some of her pain may have been due to breast cancer medication which she discontinued after a discussion with her oncologist. *Id.* at 11. Obtaining improvement with physical therapy (“PT”), Petitioner’s last visited her orthopedist in early August 2016. *Id.* at 8-13.
- The medical record from a July 12, 2018 visit to Petitioner’s primary care provider (“PCP”) includes a list of current vaccines: a pneumococcal conjugate vaccine dated September 7, 2016, a flu vaccine dated October 20, 2016, and a vaccine dated October 26, 2017. Exhibit 5 at 121. All entries list the site of vaccination as Petitioner’s *left* deltoid, but only the entry related to the pneumococcal conjugate vaccine contains a notation providing the name of a vaccine administrator. *Id.*
- On October 25, 2019, Petitioner received the flu vaccine alleged as causal at a CVS Pharmacy. Exhibit 1. The vaccine record initially provided appears to be a printed copy of the information contain in the CVS Pharmacy system, and indicates the vaccine was administered in Petitioner’s *left* deltoid. *Id.* at 6.
- Later obtained documentation from CVS in response to a subpoena indicates the flu vaccine was administered in Petitioner’s *right* arm. Exhibit 24 at 4. This documentation also contains entries related to the two flu vaccines listed in Petitioner’s July 12, 2018 PCP record, showing they were administered the next day in Petitioner’s *right* arm (*id.* at 1-2), as well as another flu vaccine also administered in Petitioner’s *right* arm on September 29, 2018. (*id.* at 3).
- On January 20, 2020 - almost three months after receiving the flu vaccine alleged as causal - Petitioner visited a new orthopedist, complaining of mild to moderate right shoulder pain after receiving a flu vaccine on October 31, 2019. Exhibit 8 at 2. She also reported “mild pain and stiffness in her neck with movement.” *Id.* Within this same record, under injury details, the date of injury is listed as November 2019. *Id.* Assessing Petitioner as suffering

⁶ An osteophyte is “a bony excrescence or osseous outgrowth.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY (“DORLAND’S”) at 1348 (32th ed. 2012).

from SIRVA, as well as cervical strain, spondylosis,⁷ right shoulder impingement, and biceps tendinitis, the orthopedist prescribed PT, instructed Petitioner to apply moist heat and ice, and discussed the possibility of an MRI if her symptoms continued. *Id.* at 3.

- On her PT intake form, completed the next day (January 21st) Petitioner described her current complaint as “[p]ain in [her] right arm since [the] flu shot [on] 11/1/2019.” Exhibit 4 at 31. When discussing her prior history with the orthopedist, she also reported “feeling intermittent tingling down into her forearm [which] [s]he had experienced . . . in the past following a neck injury.” *Id.* Regarding this prior symptom, Petitioner indicated her “[r]adicular symptoms had resolved in the past with PT.” *Id.*
- When pursuing massage therapy on February 5th, Petitioner again reported a “flu shot injury.” Exhibit 2 at 4. Attributing her right shoulder pain to this injury, she identified the date of injury and/or flu vaccine as October 2019. *Id.* at 4, 12, 14-15. Although Petitioner listed multiple areas of joint pain (*id.* at 14) and sometimes received massage therapy on her neck and upper back as well as right shoulder, the primary focus of her treatment was the right shoulder. See *id.* at 4-12.
- On February 19, 2020, Petitioner returned to the orthopedist for continued right shoulder and neck pain. Exhibit 8 at 6. An MRI performed that day revealed supraspinatus and infraspinatus tendinosis with focal bursitis sided supraspinatus tendon tear, . . . [m]ild thickening in the inferior glenohumeral ligaments, . . . [and] [l]ow lying acromial process with subdeltoid bursitis.” Exhibit 4 at 28. In the history portion of the MRI report, right shoulder pain since October 2019 is indicated. *Id.*
- From late February through March 2020, Petitioner also received acupuncture treatment for right shoulder and knee pain, as well as occasional ankle and headache pain and abdominal issues. Exhibit 2 at 18-27.
- At her third orthopedic visit on May 11, 2020, Petitioner reported that she had not been attending PT due to the COVID pandemic, but had been performing exercises at home. Exhibit 8 at 10. The orthopedist discussed

⁷ Spondylosis is “degenerative spinal changes due to osteoarthritis.” DORLAND’S at 1754.

the results of Petitioner's MRI and possibility of arthroscopic surgery and rotator cuff repair. *Id.*

- On August 12, 2020, Petitioner visited an orthopedic surgeon for a complaint of right shoulder pain after receiving a flu vaccine on October 25, 2019. Exhibit 11 at 4. When providing her history, Petitioner reported that she "is also dealing with a cervical issue that she thinks has been exacerbated by this" – her right shoulder injury. *Id.* After examining Petitioner, the orthopedic surgeon indicated that he believed Petitioner "would benefit from continued conservative management with an injection at this time." *Id.* at 8. He administered a subacromial injection and instructed Petitioner to return for further discussion of her surgical options if her symptoms returned. *Id.*
- In her witness statements, Petitioner indicated that she requested the vaccine be administered in her *right*, rather than *left*, deltoid, just before receiving the vaccination, due to the removal of her left-side lymph nodes during a bilateral mastectomy in 2003. Exhibits 9 at 1-2; 17 at 1-2. She also reported acute pain immediately upon vaccination. Exhibits 9 at 2; 17 at 2.
- Petitioner's husband and friend provided witness statements echoing Petitioner's claims regarding administration and pain onset. Exhibit 18 at 1-2 (husband's statement); Exhibit 25 (friend's statement).
- Petitioner's friend also indicated that she accompanied Petitioner to the pharmacy when receiving an earlier flu vaccine on October 21, 2016. Exhibit 25 at ¶ 3. Stating that Petitioner "always specifically tells every pharmacist to administer vaccines in her right arm" (*id.* at ¶ 4), she indicated that, on October 21, 2016, she "saw the CVS pharmacist who sat on [Petitioner's] right side give her the flu shot in her right arm" (*id.* at ¶ 5).

In every post-vaccination record containing a medical history, from the time she first sought treatment in January 2020, Petitioner *consistently* described right shoulder pain upon vaccination. Without fail, she attributed her injury to the flu vaccine she received. Although she sometimes mistakenly indicated that she received the vaccination on October 31st or November 1st, her situs contentions are corroborated consistently. While these entries were based upon information provided by Petitioner, they still should

be afforded greater weight than more current representations, as they were uttered contemporaneously with Petitioner's injury for the purposes of obtaining medical care.⁸

Additionally, Petitioner has provided a compelling reason why she would request that any vaccine be administered in her *right*, rather than *left* deltoid - the removal of her left-sided lymph nodes in 2003. And she has provided signed declarations from her husband and a friend who often accompanied her when receiving other vaccinations which prove further supporting evidence of this routine request.

The only evidence which points to administration in Petitioner's *left* arm is the July 2018 list of prior vaccinations describing three earlier vaccines as administered in Petitioner's left deltoid, and the initial record from Petitioner's October 25, 2019 vaccination. Exhibit 1 at 6. However, the list of prior vaccines has little probative value because the designations related to vaccination situs appear to have been made when the vaccines were ordered, and one day prior to when they were administered at CVS.

The initial vaccine record is more credible, but still countered by the more detailed record provided in response to a subpoena indicating a right arm situs, as Petitioner contends. Based upon my experience resolving SPU SIRVA cases (approximately 1,300 cases since my appointment as Chief Special Master) as well as additional SIRVA cases handled in chambers, I find it is not unusual for the information regarding site of vaccination in computerized systems to be incorrect. Many of these systems use a "dropdown" menu to enter information, and the relevant fields are often not updated each time a separate vaccine is administered to a different individual. See, e.g., *Mezzacapo v. Sec'y of Health & Hum. Servs.*, No. 18-1977V, 2021 WL 1940435, at *6 (Fed. Cl. Spec. Mstr. Apr. 19, 2021)⁹; *Desai v. Sec'y of Health & Hum. Servs.*, No. 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); *Rodgers v. Sec'y of Health & Hum. Servs.*, No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); *Stoliker v. Sec'y of Health & Hum Servs.*, No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018). Later provided and more detailed documentation, such as the consent form, tends to be more reliable.

⁸ The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this information even when the information is provided by Petitioner.

⁹ In this ruling by another special master, the pharmacist who had administered the relevant vaccination testified that she inputs "left deltoid" into the computer system as a matter of course, without confirming the actual site of vaccination, because most vaccinees are right-handed. *Mezzacapo*, 2021 WL 1940435, at *6. The pharmacist's testimony was deemed credible, and the site of vaccination found to be as the petitioner alleged, rather than what was indicated in the vaccine record.

I find the detailed record produced by CVS in response to the served subpoena (and which identifies the site of vaccination as Petitioner's right arm, as she alleges) to be more persuasive. Coupled with Petitioner's consistent reports of administration in her right deltoid contained in the contemporaneously-created medical records, and the evidence supporting her assertion that she routinely requests a right deltoid administration and received prior vaccinations in that arm, I find Petitioner has provided preponderant evidence supporting a right arm situs. Additionally, Petitioner's similar reports of pain upon vaccination are sufficient to establish an immediate pain onset.

V. Scheduling Order

During a telephonic status conference held in late July 2022, Respondent indicated he may be interested in settlement discussions if I were to determine the record contained sufficient evidence to support Petitioner's allegations regarding situs. In early 2022, Petitioner was working to finalize her demand (ECF No. 20), but has not yet indicated that a demand has been conveyed to Respondent.

Petitioner shall file a status report updating me on the parties' efforts to informally settle this case, including her efforts to finalize her demand by no later than Friday, April 28, 2023.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master